IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

MOSE LARSEN *et al.*

Appl. No. 09/297,040

§ 371 Date: July 21, 1999

For: **Diabetes-Mediating Proteins and Therapeutic Uses Thereof**

Art Unit: 1653

Examiner: Robinson, H.

Atty. Docket: 2012.0390004/JAG/TJS
(formerly 0785.0390004/JAG/TJS)

Reply to Restriction Requirement

Commissioner for Patents
Washington, D.C. 20231

Sir:

In reply to the Office Action dated June 12, 2001, requesting an election of one invention to prosecute in the above-referenced patent application, the period for reply having been extended two (2) months by petition and payment of the appropriate fee, Applicants hereby provisionally elect to prosecute the invention of Group II, represented by claims 7-~~14~~ 13. This election is made without prejudice to or disclaimer of the other claims or inventions disclosed.

This election is made with traverse.

Applicants point out that claim 21 is not assigned to any of the restriction groups. Accordingly, Applicants request that the Examiner indicate, in the next communication, which group encompasses claim 21. Applicants will nevertheless address the merits of the present Restriction Requirement.

The above-captioned application is a national stage of a PCT application; therefore, PCT unity of invention rules apply. *See* Manual of Patent Examining Procedure ["MPEP"] § 1893.03(d) (Seventh ed., rev.1, February 2000). PCT Rule 13.2

states that the requirement of unity of invention is fulfilled when there is a "technical relationship among those inventions involving one or more of the same or corresponding special technical features." *See* MPEP, Appendix T at T-44. More specifically, Annex B Part 2 of the PCT Administrative Instructions, as amended July 1, 1992, states that "[t]he method for determining unity of invention under Rule 13 shall be construed as permitting, in particular . . . in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product." *See* MPEP at AI -36 to AI-37.

The diabetes-mediating proteins of Group II (claims 7-13) are characterized as exhibiting an altered expression during the development of diabetes, relative to expression of the same protein in the absence of diabetes. As will be understood from the application document as a whole, the presence or absence of these proteins correlate to diabetes in a mammal. One characteristic feature is thus their ability to serve as indicator- or marker proteins for diabetes.

Claims 1-6, 14 and 15 are drawn to various processes for identifying a diabetes-mediating protein (claims 1-5, 14 and 15) and an isolated diabetes-mediating protein identified by such process (claim 6). Claims 12-13 are drawn to the use of said proteins for their characteristic properties in a comparative analysis. Claims 12-13 are thus drawn to a process for the use of the proteins. Moreover, claims 22-23 relate to the use of the diabetes-mediating proteins to treat or prevent diabetes or a diabetes-related disorder,

comprising administering said protein. Accordingly, claims 7-11, 1-6, 14, and 15, and 12-13, and 22-23 are all related as directed either to diabetes-mediating proteins, to processes specially adapted for the manufacture (e.g. identification and isolation) of such proteins, or to uses for said proteins. The special technical feature common to all of these claims is the diabetes-mediating nature of the proteins. In this regard, Example 1 set forth in Annex B Part 2 of the PCT Administrative Instructions, as amended July 1, 1992, is instructive. *See* MPEP at AI-39.

Furthermore, claim 20 relates to the use of an antibody to the proteins in a method of treating diabetes. The antibody and the protein have a complementary relationship analogous to a plug and socket in PCT Administrative Instructions, Annex B, part 2, Example 8, or between transmitter and receiver in Example 9 thereof.

In view of the above, Applicants respectfully request reconsideration and withdrawal of the Restriction Requirement, and a reformulation of the restriction groups. At a minimum, the Examiner should examine claims 19, and 22-25, directed to use of the proteins, and claims 1-6, 14 and 15, directed to methods of identifying proteins with the claims of Group II.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees

required therefor are hereby authorized to be charged to our Deposit Account No. 19-0036.

Respectfully submitted,

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Date: September 12, 2001

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